UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

- -

JENNIFER L. MARSHALL,

Plaintiff,

v. 5:12-cv-721

I-FLOW, LLC
f/k/a I-FLOW CORPORATION,

Defendant.

- -

THOMAS J. McAVOY
Senior United States District Judge

DECISION and ORDER

Plaintiff Jennifer Marshall commenced the instant action against Defendant I-Flow, LLC arising out of personal injuries she is alleged to have sustained as a result of using Defendant's pain pump to inject an anaesthetic into the joint space of her right shoulder. Presently before the Court is Defendant's motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) seeking dismissal of Plaintiff's claims of fraud, strict product liability, strict tort liability, breach of implied warranty, and punitive damages.

I. FACTS

As of June 7, 2006, Plaintiff Jennifer Marshall was a 42 year old woman. Plaintiff consulted with Tamara A. Scerpella, M.D., an orthopedic surgeon, concerning a problem she was experiencing with her right shoulder. Scerpella recommended surgical intervention, to which Marshall consented.

On July 6, 2006, Plaintiff underwent a right shoulder arthroscopic surgery at Harrison Center Outpatient Surgery in Syracuse, New York. During the surgery, Dr. Scerpella noted that the "glenohumeral articular surfaces were entirely intact." Following surgery, Dr. Scerpella inserted an I-Flow ON-Q PainBuster, REF: PM012, LOT: 642472 ("ON-Q"), pain pump into Plaintiff's shoulder joint to continuously infuse local anesthetic into the joint space. The ON-Q continuously infused 100 ml of 0.5% Marcaine directly into Plaintiff's right shoulder joint for forty-eight hours or more following her surgery.

After a period of time, Plaintiff began to experience increased pain in her right shoulder. She was initially treated with physical therapy. As Plaintiff's pain worsened, x-rays were taken on January 26, 2009, which showed "arthritic changes involving the glenohumeral joint with some bony eburnation and joint space narrowing." Degenerative changes to the acromioclavicular joint also were noted.

Plaintiff went to Ilya Voloshin, M.D., an orthopedic surgeon for further evaluation and possible treatment. Voloshin recommended right shoulder arthroscopy, to which Plaintiff agreed. On August 1, 2011, Plaintiff underwent a right shoulder arthroscopic acromioplasty and extensive glenohumeral debridement at Strong Memorial Hospital in Rochester, New York. During the surgery, Dr. Voloshin observed "[g]rade 4 cartilage damage on the entire glenoid" and "[g]rade 2 to 3 chondral damage on the humeral head." After surgery, Dr. Voloshin informed Plaintiff that she would need a total right shoulder replacement. An MRI taken of Plaintiff's right shoulder on October 3, 2011 showed "severe glenohumeral joint osteoarthritis with complete loss of cartilage centrally and posteriorly with extensive subchondral cystic changes on both sides of the joint."

On November 7, 2011, Plaintiff was evaluated by orthopedic surgeon Mark V. Wilson, M.D. of Vestal, New York on November 7, 2011. Dr. Wilson diagnosed “severe glenohumeral osteoarthritis” of her right shoulder. Dr. Wilson referred Plaintiff to orthopedic surgeon Kevin J. Setter, M.D. of Syracuse. On January 3, 2012, Plaintiff presented to Dr. Setter for an evaluation and possible treatment. Dr. Setter recommended that Plaintiff undergo a total shoulder replacement should her symptoms continue.

Plaintiff contends that the continuous injection of anesthetic drugs over time directly into her shoulder joint after the July 6, 2006 surgery caused serious and permanent cartilage damage. It is alleged that, as a result of the continuous injection of the anesthetic, Plaintiff suffered a narrowing of the joint space and/or a condition called "glenohumeral chondrolysis," which is the complete, or nearly complete, loss of cartilage in the shoulder joint, an irreversible, disabling, and extremely painful condition.

Plaintiff claims that Defendant is liable to her because Defendant misled the medical community, the public at large, Plaintiff, and her treating physicians, by making false representations concerning the safety and proper use of its product. In support, Plaintiff claims that Defendant failed to conduct any testing concerning the safety of its product; did not review available literature concerning the safety of its product; sought, and failed to obtain, FDA clearance for an indication for use in intra-articular spaces; failed to advise that the safety of pain pumps in a joint space was unknown; and failed to warn of known and/or knowable risks associated with the use of its product. Plaintiff asserts claims of negligence, negligent misrepresentation, fraud, strict product liability (defective design and failure to warn), and breach of an implied warranty.

Presently before the Court is Defendant's motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c). Plaintiff opposes the motion.

II. STANDARD OF REVIEW

As the Second Circuit has explained:

> In deciding a Rule 12(c) motion, [courts] "employ[ ] the same . . . standard applicable to dismissals pursuant to [Rule] 12(b)(6). Thus, [the court] will accept all factual allegations in the [C]omplaint as true and draw all reasonable inferences in [Plaintiff's] favor." Johnson v. Rowley, 569 F.3d 40, 43 (2d Cir. 2009) (quotation marks and citation omitted).
>
> In Ashcroft v. Iqbal, the Supreme Court set forth a "two-pronged approach" to evaluate the sufficiency of a complaint. 129 S.Ct. at 1949-50. "First, although a court must accept as true all of the allegations contained in a complaint, that tenet is inapplicable to legal conclusions, and threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Harris v. Mills, 572 F.3d 66, 72 (2d Cir. 2009) (quotation marks and alterations omitted). "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss, and determining whether a complaint states a plausible claim for relief will ... be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. (quotation marks and alteration omitted). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 129 S. Ct. at 1949 (quotation marks omitted). Plausibility thus depends on a host of considerations: the full factual picture presented by the complaint, the particular cause of action and its elements, and the existence of alternative explanations so obvious that they render plaintiff's inferences unreasonable. See id. at 1947-52.

L-7 Designs, Inc. v. Old Navy, LLC, 647 F.3d 419, 429-30 (2d Cir. 2011)

III. DISCUSSION

a. Choice of Law

The first issue is one of choice of law. Plaintiff, a New York resident, commenced this litigation against Defendant, a California corporation, in a court in the District of Columbia, arising out of events occurring in the State of New York. Applying the District of Columbia's choice of law rules, the Court finds that New York law applies because: (1)

Plaintiff is a New York resident; (2) Plaintiff was injured in New York; (3) the conduct causing the injury occurred in New York ; (4) Defendant does business in New York; (5) the relationship between the parties is centered in New York; (6) New York has the greatest interest in this action; and (7) New York's policies would be most advanced by having its law applied to the facts of this case. Stutsman v. Kaiser Foundation Health Plan of Mid-Atlantic States, Inc., 546 A.2d 367, 372-3 (D.C. Ct. of App. 1988); see also Sheffer v. Novartis Pharmaceuticals Corp., — F. Supp.2d —, —, at 2012 WL 2775027, *7 (D. D.C. 2012).

b. Implied Warranty Claim

Defendant moves to dismiss the breach of the implied warranty claim on the ground that it is barred by New York's four year statute of limitations. Defendant argues that the limitation period commenced no later than the time when the surgery was performed (July 6, 2006) and, therefore, because the instant action was not commenced until January 19, 2012, it is well after the four year statute of limitations. Plaintiff responds that Defendant's fraudulent concealment tolled the statute of limitations for the breach of implied warranty claim. Plaintiff further contends that, because this case was initially commenced in the District of Columbia and transferred to this District pursuant to 28 U.S.C. § 1404(a), this Court should apply D.C.'s statute of limitations.

For the reasons previously discussed, the Court will apply New York law. The rule in New York is that a breach of implied warranty claim must be commenced within four years from the date the defendant tendered delivery of the product. Heller v. U.S. Suzuki Motor Corp., 64 N.Y.2d 407 (1985); Vanata v. Delta Intern. Machine Corp., 269 A.D.2d 175, 176 (1st Dept. 2000). Here, the product was delivered no later than the date of surgery - July 6, 2006. Because the instant action was not commenced until 2012, it is beyond the four year

limitation period. No exception to this general rule applies here. Even applying D.C. law, this claim would be time-barred. See Hunt v. DePuy Orthopaedics, Inc., 636 F. Supp.2d 23, 27 (D. D.C. 2009).[1] Accordingly, the implied warranty claim is dismissed.

c. Fraud Claim

1. Rule 9(b)

Defendant also moves to dismiss the fraud claim on the ground that the Complaint fails to comply with Fed. R. Civ. P. 9(b). Plaintiff responds that it has adequately met the pleading requirements of Rule 9(b).

Rule 9(b) "requires particularity when pleading fraud . . . , while allowing "[m]alice, intent, knowledge, and other conditions of a person's mind [to] be alleged generally." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1954 (2009). To meet this requirement, the Complaint must: (1) specify the statements that Plaintiff contends are fraudulent; (2) identify the speaker; (3) state where and when the statements were made; and (4) explain why the statements were fraudulent.

[1] The allegations in the Complaint are insufficient to demonstrate that Defendant fraudulently concealed the basis of a cause of action, thereby warranting tolling of the statute of limitations. William J. Davis, Inc. v. Young, 412 A.2d 1187, 1191 (D.C. Ct. App. 1980). To toll the statute of limitations, "the defendant must have done something of an affirmative nature designed to prevent discovery of the cause of action." Id. Although it is claimed that Defendant told physicians and the public that its product was safe, did not disclose the FDA's rejection of use of the I-Flow in the joint, promoted the I-Flow for use in joints, did not conduct safety studies, and was aware of problems using the pump in the joint, this is insufficient to demonstrate fraudulent concealment of a potential cause of action. Plaintiff states that in August 2007, well within the statute of limitations period, Defendant posted "[a] Technical Bulletin warning about pain pumps and chondrolysis." Pl. Mem. of Law at 7; Compl. at ¶ 76. See Cevenini v. Archbishop of Washington, 707 A.2d 768, 773-43 (D.C. Ct. of App. 1998) ("Rather than alleging affirmative acts of concealment . . ., [plaintiffs] have asserted only that the [defendant] failed to disclose information to them. . . . Such assertions . . . do not constitute the 'affirmative acts'. . ." necessary to establish fraudulent concealment.). Even if tolling applied, it would only apply until the issuance of the August 2007 Technical Bulletin. This additional time is insufficient to save Plaintiff's implied warranty claim.

Accepting the allegations in the Complaint as true and drawing all reasonable inferences in favor of Plaintiff, the Court finds that the Complaint adequately meets Rule 9(b)'s particularity requirements. Plaintiff identifies the following statements as fraudulent: (1) a press release issued on September 2, 1998 stating that I-Flow had received approval in June 1998 from the U.S. Food and Drug Administration to market the PainBuster in the United States for orthopedic surgery applications, when, in fact, I-Flow never received any such approval; (2) marketing statements that the I-Flow was safe for use in joints, when, in fact, I-Flow did not have information whether the pump was safe for orthopedic uses; (3) a 2001 PowerPoint presentation stating that the pump was particularly useful in shoulder and other joint surgery; and (4) marketing of the I-Flow at Harrison Center Outpatient Surgery, where Plaintiff had her surgery for, intra-articular use. This satisfies the first and third elements of Rule 9(b).

Turning to the second element, the speaker is identified as I-Flow, through its agents, which is sufficient where the defendant is a corporation, the corporation is alleged to have made the fraudulent statements, and the corporation is in the best position to know who the actual speakers were. Talavera v. Metabolife Intern., Inc., 2004 WL 2260628, at *2 (N.D. Ill. Sept. 24, 2004).

With respect to the last element, the Complaint alleges that Defendant knew that: (1) use of a pain pump in the shoulder joint had been rejected by the FDA for lack of safety data; (2) there had not been any safety testing; (3) I-Flow employee, Robert Bard, admitted that the FDA had rejected three attempts to secure synovial cavity use for the pump; (4) numerous scholarly articles were published identifying safety issues with using pain pumps on shoulder cartilage; and (5) surgeons were reporting incidents of chondrolysis after pain

pump use of which I-Flow was aware. These allegations adequately demonstrate why the statements were false; namely, that the pain pump was not safe despite Defendant's representations to the contrary. See Ashcroft v. Iqbal, 556 U.S. 662, 686, 129 S. Ct. 1937, 1954 (2009).

2. Causation

Defendant next moves to dismiss the fraud claim on the ground that Plaintiff fails to establish that she justifiably relied on Defendant's representations. In support, Defendant argues that it never made any statements to Plaintiff directly and it is not liable for representations to patients or the public generally because the physician is the relevant decision-maker.

Defendant's reliance on the informed intermediary doctrine is misplaced. The informed intermediary doctrine provides that a manufacturer discharges its duty to warn by providing adequate warnings to the prescribing physician, who then acts as an informed intermediary between the manufacturer and the patient. Bukowski v. CooperVision, Inc., 185 A.D.2d 31, 34 (3d Dept. 1993); see also Fane v. Zimmer, Inc., 927 F.2d 124, 129 (2d Cir. 1991). If a manufacturer provides adequate warnings to the physician, "the product is not defective." Fane, 927 F.2d at 129.

The claim under review is one for fraud; not a defective product. It is claimed that Defendant made material misrepresentations to the public and to physicians, including Plaintiff's physician, who relied upon such representations in making the decision to use the I-Flow on Plaintiff. Any false representations made to, and relied upon, by Plaintiff's physician in making the decision to use the I-Flow and resulting in injuries to Plaintiff (which the Complaint sufficiently alleges) give rise to a cause of action in fraud.

d. Strict Liability Claim

Defendant moves to dismiss the strict liability claim on the ground that it is duplicative of a negligent failure to warn claim. The Court disagrees.

"Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent." Id. at n.1. The New York Court of Appeals has stated that, in the case of prescription items, "[t]he manufacturer's duty is to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." Martin v. Hacker, 83 N.Y.2d 1, 8 (1993). A prescription item is "by its nature an inherently unsafe product and would in the usual case impute strict liability to its manufacturer. . . ." Id.; see also Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 62 (4th Dept. 1979), aff'd, 417 N.E.2d 1002 (1980) ("New York's well-established rule governing the field of products liability . . . [applies] with equal affect to the marketing for public consumption of prescription [products]."). The law provides a defense against strict liability when the product is properly prepared and accompanied by proper directions and warning. Id.

Here, Plaintiff's Complaint alleges that Defendant failed to reasonably apprise itself of the dangers of using its product in joints and failed to warn of the dangers of doing so. Plaintiff claims that the I-Flow was not accompanied by proper directions and warnings. This properly states a claim under New York law, whether it is labeled as a strict liability claim or a claim sounding in negligence. That being said, because the failure to warn claims are equivalent under negligence or strict liability, Plaintiff will not be permitted to recover twice and will have to choose one label for her claim before any claims are presented to the trier of fact.

e. Punitive Damages Claim

Lastly, Defendant moves to dismiss the punitive damages claim on the ground that the law does not recognize an independent cause of action for punitive damages. Plaintiff concedes the point, provided punitive damages remain available to her as damages to her other claims. Because there is no independent claim for punitive damages and Plaintiff remains free to seek such damages in connection with her other claims, Plaintiff's Eighth Cause of Action is dismissed.

IV. CONCLUSION

For the foregoing reasons, Defendant's motion is GRANTED IN PART and DENIED IN PART. Defendant's motion is granted insofar as the sixth and seventh causes of action are DISMISSED. In all other respects, the motion is DENIED.

IT IS SO ORDERED.

Dated:August 7, 2012

Thomas J. McAvoy
Senior, U.S. District Judge